K102961

Exactech® Novation® Empire™ Acetabular Augments
Traditional 510(k) – 510(k) Summary

510(k) Summary

Company:	Exactech®, Inc 2320 NW 66th Court Gainesville FL, 32653
Date:	September 17, 2010
Contact Person:	Darrell Kassner Director, Regulatory Affairs Telephone: (352) 377-1140 Fax: (352) 378-2617
Proprietary Name:	Exactech® Novation® Empire™ Acetabular Augments with InteGrip™
Common Name:	Acetabular Augment
Classification Name:	21 CFR 888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. Device Class: II, Classification Panel: Orthopedic, Product Code: LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented

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Legally Marketed Devices to Which Substantial Equivalence Is Claimed

- Zimmer Hedrocel Acetabular Augment, 510(k) K001471

Device Description

The proposed acetabular augments are manufactured by an additive manufacturing process from titanium alloy to create a porous structure designed to provide initial mechanical fixation in addition to the potential for long-term biological fixation. The augments feature holes that allow for the use of 4.5mm bone screws for adjunct fixation of the acetabular augment and the surrounding bone. The acetabular augments are available in 3 heights (8mm, 11mm, and 13mm) and cover acetabular shell outer diameter sizes 48-58mm.

The proposed augments mate with the following devices:

- Novation Crown Cup acetabular shells (K070479)
- Exactech Bone Screws (K896601).

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Indications for Use
The Empire Acetabular Augments are indicated for use in skeletally mature individuals undergoing primary or revision surgery for hip replacement and whose orthopedic surgeon desires a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies.

The Empire Acetabular Augment is affixed to the mating acetabular shell using PMMA bone cement. *Therefore, acetabular shells with HA coating must not be used with Empire Acetabular Augments.* The assembled construct is intended for press-fit fixation. The construct may also be used with bone cement at the discretion of the surgeon.

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use.** The proposed Empire Acetabular Augments and predicate Zimmer Hedrocel Acetabular Augments are intended for use as a prosthetic alternative to structural allograft in cases of segmental acetabular deficiencies and have similar indications for use statements.
- **Materials.** The proposed Empire Acetabular Augments and predicate Zimmer Hedrocel Acetabular Augments are composed of materials conforming to recognized industry standards for permanent implants.
- **Sterilization processes.** The proposed Empire Acetabular Augments and predicate Zimmer Hedrocel Acetabular Augments are provided sterile for single use and conform to recognized industry standards.
- **Design Features.** The proposed Empire Acetabular Augments and predicate Zimmer Hedrocel Acetabular Augments incorporate similar design features.
- **Performance specifications.** The proposed Empire Acetabular Augments and predicate Zimmer Hedrocel Acetabular Augments conform to recognized performance standards for total hip replacement devices.

Substantial Equivalence Conclusion
Results from mechanical tests, animal studies, simulated-use tests, and engineering analyses demonstrate the proposed Empire Acetabular Augments are substantially equivalent to the predicate Zimmer Hedrocel Acetabular Augments. A summary of these tests and analyses are as follows:

- Cadaver lab validation demonstrating the design features (including outside geometry and overall scope).
- Test summary and reports of the material based on *FDA Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement.*
- Animal study report comparing the biological fixation characteristics of the porous Ti-6Al-4V to historical data.
- Clinical literature review of predicate acetabular augment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Exactech, Inc.
% Mr. Darrell J. Kassner
Director, Regulatory Affairs
2320 N.W. 66th Court
Gainesville, Florida 32653

SEP 21 2010

Re: K101761
Trade/Device Name: Exactech® Novation® Empire™ Acetabular Augments with InteGrip™
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Codes: LPH, JDI, LWJ, LZO
Dated: June 21, 2010
Received: June 23, 2010

Dear Mr. Kassner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Bruch for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K101761

Device Name: Exactech® Novation® Empire™ Acetabular Augments with InteGrip™

INDICATIONS FOR USE:
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Prescription Use __X__ **and/or** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101761